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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/782,794	02/13/2001	Michael K. Kwan	07078-003003	9975

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FISH & RICHARDSON P.C.
500 ARGUELLO STREET, SUITE 500
REDWOOD CITY, CA 94063

EXAMINER

BLANCO, JAVIER G

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 04/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/782,794

Applicant(s)

KWAN ET AL.

Examiner

Javier G. Blanco

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19,20,24 and 25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19,20,24 and 25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 27, 2003 has been entered as Paper # 14.

Oath/Declaration

2. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02. The oath or declaration is defective because there is no priority claim to provisional application 60/005,523 filed October 16, 1995.

Priority

3. This application filed under former 37 CFR 1.60 lacks the necessary reference to the prior application. A statement reading "This is a continuation of Application No. 09/110,726, filed July 7, 1998, now US 6,187,047, which is a division of Application No. 08/633,554 filed April 17, 1996, now US 5,776,193." should be entered following the title of the invention or as the first sentence of the specification. Also, the current status of all non-provisional parent applications referenced should be included.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 19, 20, 24, and 25 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Rhee et al. (US 5,264,214). Rhee et al. disclose the method of bone repair comprising applying a porous, biodegradable, three-dimensionally stable matrix having shape retention comprising fibrillar collagen, polyethylene glycol (or gelatin), and hydroxyapatite (see column 4, lines 62-68; column 5, lines 3-6 and lines 18-21; column 6, lines 55-59; column 7, lines 37-45 and lines 65-68).

Response to Arguments

6. Regarding 102(b) rejection over Rhee et al. '214, Applicant's arguments filed March 27, 2003 have been fully considered but they are not persuasive. Applicants argue that Rhee et al.'s biopolymer "is not mineralized, but rather is merely mixed with particulate materials".

Applicants also argue that the mineral in Rhee et al.'s biopolymer is not immobilized on the matrix. Examiner respectfully disagrees:

a. Merriam-Webster's Collegiate Dictionary (Tenth Edition) defines the word "mineralized" as: "to impregnate or supply with minerals or an inorganic compound". Rhee et al. '214 disclose "Compositions comprising collagen-polymer with ceramic particles, preferably hydroxyapatite and/or tricalcium phosphate, are particularly useful for repair of stress-bearing bone due to its

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high tensile strength.” (see column 6, lines 55-59). Rhee et al. ‘214 also disclose “A formulation useful for repair of stressbearing bone defects (e.g., fractures, nonunions, and the like) may be prepared by mixing collagen-PEG of the invention with a suitable particulate, insoluble component. The insoluble component may be fibrillar crosslinked collagen, gelatin beads, polytetrafluoroethylene beads, silicone rubber beads, hydrogel beads, silicon carbide beads, mineral beads, or glass beads, and is preferably a calcium mineral, for example hydroxiapatite and/or tricalcium phosphate.” (see Example 7, column 20, lines 34-43). These teachings clearly show that the biopolymer is mineralized since Rhee et al. ‘214 disclose impregnating or supplying the biopolymer with minerals (i.e., hydroxyapatite).

b. Merriam-Webster’s Collegiate Dictionary (Tenth Edition) defines the word “immiscible” as: “incapable of mixing or attaining homogeneity”. Rhee et al. ‘214 disclose that the particulate material (i.e., minerals) is immiscible with the collagen-polymer matrix (see column 7, lines 37-40). Rhee et al. ‘214 also disclose that the collagen-polymer-particulate compositions may be malleable or rigid, depending on the application (i.e., a rigid composition/formulation may be used for the treatment of stress-bearing bone defects; see column 9, lines 32-46; column 12, lines 52-65; column 20, lines 34-48). Since Rhee et al. ‘219 disclose (i) rigid collagen-polymer-particulate compositions/formulations, and, (ii) the mineral(s) as immiscible with the collagen-polymer matrix, it is then clearly shown that the mineral is immobilized on the matrix.

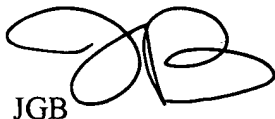
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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Javier G. Blanco whose telephone number is 703-605-4259. The examiner can normally be reached on M-F (8:00 a.m.-5:30 p.m.), first Friday of the bi-week off.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 703-308-2111. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9302 for regular communications and 703-872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.



JGB

April 19, 2003



David H. Willse
Primary Examiner